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New Turkish Regulation Blocks Imports of Biotech Food and Feed

Report Categories:

Biotechnology

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Report Highlights:

A new regulation published in the Official Gazette on October 26, 2009 effectively blocks imports of biotech food and feed to Turkey. An unofficial translation of the text is provided below.

Summary:

Turkey did not have any regulations related to agricultural biotechnology in force until October 26, 2009, and imports of transgenic commodities entered Turkey without hindrance. On October 26, 2009, the Ministry of Agriculture and Rural Affairs published a regulation covering biotechnology in food and feed. The regulation, which was not made public in advance and contains no phase-in period, effectively blocks all imports of food and feed that might contain genetically-engineered material, pending approval by an as-yet non-existent committee. Several other requirements would create procedural barriers. The approval system,

as described, does not appear to be based on standard international risk assessment procedures.

The total value of U.S. transgenic crops exported to Turkey in 2008, including cotton, corn, soy and their derivatives, was valued at more than \$1 billion.

An unofficial translation of the regulation follows, as well as an unofficial translation of a Ministry of Agriculture press release issued on October 27. The official text of the regulation is available (in Turkish only) online in the Official Gazette 27388 at the following website: <http://rega.basbakanlik.gov.tr/>

Food Laws:

Unofficial Translation

October 26, 2009

Official Gazette: 27388

Regulation on the Import, Processing, Export, Control and Inspection of Food and Feed Products Bearing GMOs and GMO Components

SECTION-1

Objective, Scope, Legal Basis and Definitions

Objective

Article- 1 – (1) This directive determines the implementation of rules and principles of the decision making, processing, import, export, surveillance, registration, labeling, control and inspection services in regards to the food and feed that include the genetically modified organisms or include ingredient that contain a component of genetically modified organism or food and feed produced from genetically modified organisms in order to protect human life and health, animal health and welfare, consumer benefits and environment at the highest level.

Scope

Article- 2 – (1) This directive comprise of the implementation of rules and principles of the decision making, processing, import, export, surveillance, registration, labeling, control and inspection services in regards to the food and feed that include the genetically modified organisms or genetically modified organisms except seeds.

(2) This does not include products approved and licensed by Ministry of Health.

Legal Basis

Article- 3 – (1) This directive is based on the Article-10 of the Agriculture Law (Number 5488), Decree Having the Force of Law on Establishment and Duties of the Ministry of Agriculture and Rural Affairs (Number 441), Law on Adoption of the Amended Decree By-Law on the Production, Consumption and Inspection of Food (Number 5179), Feed Law (Number 1734) and Law on Preparation of Technical Regulations for Products (Number 4703).

Definitions

Article- 4 – (1) The terms mentioned in this directive are:

- a) Unique Identifier: System of codes that identify the genes,
- b) Ministry: Ministry of Agriculture and Rural Affairs,
- c) Directorate: Provincial Agricultural Directorate,
- d) GMO: Genetically Modified Organisms.
- e) Genetically Modified Organism: Organism, except human beings, whose genetic material is changed by utilization of modern biotechnology.
- f) GMO and Products: Genetically modified organisms and products that contain GMOs, are made from GMOs, contain GMOs but are not made only from GMOs and/ or partially made from GMOs.
- g) GMO Product: Product that is GMO, containing GMO or contain GMO ingredient or made from GMOs.
- h) GMO Food: Food that is GMO, containing GMO or contain GMO ingredient or made from GMOs.
- i) GMO Feed: Feed that is GMO, containing GMO or contain GMO ingredient or made from GMOs.
- j) Equivalent Product without GMOs: Equivalent food and feed that is produced without genetic modification technology,
- k) Gene Owner: One that holds the patent rights for the gene or genes that is changed in the GMO and products.
- l) Surveillance: Observation, analysis and control of GMO and products under a program in order to determine the effects on biodiversity, plant, animal and human health.
- m) Traceability: Tracing, detecting and identifying GMO and products during all the stages of the production and distribution.
- n) KKG: General Directorate of Protection and Control,
- o) Committee: An independent, scientific and technical risk assessment committee that is anticipated to be established by this regulation.
- p) Risk Assessment
- q) Risk Management
- r) TAGEM: General Directorate of Agricultural Research
- s) TUBITAK: Scientific and Technological Research Council of Turkey.
- t) TUGEM: General Directorate of Agricultural Production and Development
- u) List of Experts: The list of experts that is prepared by the Ministry, who will direct the studies.

SECTION-2

General Provisions and Conditions for Authorization

General Provisions

Article-5 (1) The import, marketing, registration, export and transit of GMO food and GMO feed for consumption and processing purposes is banned if the product is against the articles mentioned in this regulation. Customs authorities shall not ask for additional documentation regarding GMOs for products covered by this Regulation.

(2) If the imported, produced or distributed GMO food or feed is detected to harm environment, human or animal health then the food or feed processor is obliged to take necessary precautions to protect the environment, inform the Ministry, consumers and other related authorities immediately and the processor is also obliged to recall the product from the market.

(3) GMO products are banned in baby food, baby formula, continuation food and formula, food supplement for babies and young children.

(4) Import and distribution of GMOs and products that have resistance to antibiotics, which are used in treatment of human beings and animals, are banned.

(5) Ministry may direct the import and export ports for GMOs.

(6) If food or feed contains one or more GMO in total of minimum 0.9% then it is regarded as a GMO

product.

(7) The product is not approved if 0.5 percent of the product is contaminated with one or more unapproved GMO variety.

(8) Products that do not contain GMOs cannot be labeled as “GMO-free.”

(9) The Ministry has all the authority to regulate any matter and to take any precautions that are not mentioned under this directive.

Conditions for Authorization

Article-6 (1) The risk assessment is carried out only once for each GMO and it is based on the gene or genes that are modified with scientific methods.

(2) The decision document is prepared following each risk assessment showing that as a result of the research the GMO food and GMO feed is not harmful to environment, human or animal health. The decision document must have at least below matters:

- a) The validity of the approval,
- b) Policies and procedures that needs to be applied for the import of GMO and products,
- c) The purpose and restrictions of the product,
- d) Risk management, market inspection, and if needed production planning,
- e) Surveillance and traceability conditions,
- f) Documentation and labeling conditions,
- g) Packing, transportation, conservation and transfer conditions,
- h) Conditions for processing, waste and residual disposal,
- i) Security and emergency measures,
- j) Annual reporting conditions for the usage,
- k) Conditions regarding the transfer of ownership of the product,
- l) Usage and processing conditions depending on supply and purpose

(3) Ministry may ask for public comments on the Committee’s decision prior to approval.

(4) The decision of the Committee will be enforced after the approval of the Ministry.

(5) The Ministry of Agriculture shall publish the information on approved GMOs and other information on GMOs on a publicly available website.

(6) In order to register approved GMO and products and to allow traceability at every stage, the importers, processors and distributors of the GMO and products are obliged to make a declaration to the Ministry and GMO and products must meet the requirements for transfer, transportation and labeling.

(7) The approval may be canceled by the Ministry if the conditions on the decision document is violated or new scientific research is done on the risks and harms of the product and some negative outcomes are reached as a result of the usage of the product. The products are then re-called and disposed.

(8) The approval will be canceled if they don't follow the conditions on the decision document. The administrative enforcements are done depending on the reason of the cancellation.

(9) Products containing GMO cannot be used in any other way than the approved purpose.

(10) The owner of the gene is obliged to report to the Ministry and to take necessary precautions as soon as

they find out about a new risk or suspicion about a risk.

(11) The owner of the gene is responsible for informing the buyers of the security rules and precautions related to the mentioned GMO and GMO products' sale, distribution, storage, processing and packaging.

SECTION-3

Committee, Application and Working Groups

Committee

Article 7- (1) A lists of experts, who are responsible to search technical and scientific data, evaluate data and prepare reports about GMO, will be prepared by the Ministry. The term of each specialist is 2 years. The experts' list will have representatives from General Directorate of Agricultural Research (TAGEM), General Directorate of Agricultural Production and Development (TÜGEM), General Directorate of Protection and Control (KKGM), Universities, The Scientific and technical Research Council of Turkey (TUBITAK). A committee of 11 members from the experts' list is formed for each application.

(2) General Secretariat of the Committee is run by TAGEM. Committee shall have meeting by the request of TAGEM.

(3) Committee shall have meetings with the attendance of at least 9 members. Committee shall elect chairman for each application. The Committee shall take decisions with the absolute majority of those present. The justification of positive and negative decisions shall be written by the related members, signed and send it to the chairman as attachments to the decision.

(4) Committee shall make a decision about the application within 90 days after the first meeting. If the committee asks for additional documents and information, the 90 day period will be paused. The additional documents must be supplied within 30 days if committee asks for additional documents.

(5) If the committee disapproves an application, new application of the same product cannot be submitted at least one year following the disapproval date. The new application cannot be done without new scientific data.

(6) The announcement of the information to the public about application is subject to committee's approval upon the applicant's demand.

(7) The committee is responsible to Ministry for their activities.

Responsibilities and duties of committee

Article 8- (1) The responsibilities and duties of the committee are given below:

- a) Committee will evaluate the application, prepare a report and present to the Ministry.
- b) The committee is not allowed to give any information and document and is not allowed to make any statement about the application during the evaluation period without consent of the Ministry.
- c) Depending on the need, the Committee may invite one or more experts from the "experts' lists" to attend at the most two meetings and to provide advice only.

Application

Article-9 (1) In order to have the first evaluation of the GMO product by the committee, the owner of the gene has to apply to the Ministry by providing the below documents and information:

- a) Information or documents that contain data about the gene or genes that change the structure of the GMO,
- b) All kinds of information and documents and supporting documents that pave the way for the method and

reference material to detect the GMO,

c) Information on the Unique Identifier ,

d) Information and scientific research results that are related to the GMO risk assessment application

e) Information on intended use and restrictions, and information and documents to support this part of the application,

f) Information and documents that explain usage and production conditions

g) Information and documents that show risk management, auto-control and production planning,

h) Information and documents that explain monitoring and traceability,

i) Information and documents that explain confiscation conditions, and treatment of wastes

j) Safety, precautionary plan and practices and related information and documents

k) Document showing the conditions if it is allowed to transfer the ownership of the GMO product, or the product can be used by somebody else, and if so, provide conditions for transfer and usage

l) Provide storage and transfer conditions of GMO food or feed materials that are applied for,

m) Documents or certification approved by competent authority which proves that the gene or genes (which are applied for approval in Turkey) have been registered for and has been commercialized in the exporting country for at least 3 years prior to the application in Turkey.

n) Documents approved by competent authority shows that registered variety is commercially produced initially in the country where it is originally developed and other countries that have related legislations.

o) Documents and information showing that the GMO does not have a close relative variety or wild species in Turkey in order to protect Turkey's flora and fauna,

(2) Committee may ask for additional documentation if necessary.

(3) Committee shall deny the application when necessary documents and information is not supplied within the given time.

Working Groups

Article- 10 (1) TAGEM may establish working groups. TAGEM is responsible to decide on the number of the members and the duration of the meetings. The working groups, chosen from the experts' list may be formed to work on below issues:

a) To provide advice on strategies and policies that Turkey should adopt by following the international developments,

b) To make assessments on GMOs and GMO products for the sensitive consumer groups and to advice on the products,

c) To advice the Ministry on internationally consumed GMOs and products,

d) To inform necessary government bodies on risky products that are approved for production,

e) To prepare biosafety risk scenarios for the immediate term, short-term and long-term.

f) To provide advice on precautions for emergency situations depending on Turkey's needs.

SECTION-4

Import, Processing, Export, Storage, Export, Labeling Surveillance, Inspection and Control of GMO Products

Import

Article-11 (1) Below issues are considered for the import of GMOs and products that have been assessed by the Committee and their import has been approved in the Decision document:

a) A document, noting lot number, amount, and GMO type which is issued by the official authorities of the country (where GMO and products have been produced) is required.

b) If the product is shipped from a country other than the producing country, in addition to the document issued by the producing country, another document issued by the authorities of the shipping country noting the lot number, amount and GMO type is required.

c) The Ministry has the authority to analyze the shipments for control and inspection.

d) The frequency of the analyses is determined by the Ministry, based on the risk.

(2) The following principles are applied to the imports that are declared to be GMO free but have a risk of containing GMOs:

a) The products that have the potential to have GMOs are determined by the Ministry. The frequency of the analysis of these products is determined by the approval of the Ministry. This is updated by the Ministry, if needed.

b) The products are analyzed based on the determined frequency. If the analysis results are appropriate, the product is allowed to be imported.

d) If the result of the analysis is not appropriate then the product is not allowed to be imported. The importer, exporter and the exporting country of these products are added to the risk list.

(3) The importer is obliged to supply all kinds of information, documents, products and materials including analysis methods and special materials that might be needed, which are required for the evaluation and control processes.

Processing and Storage of GMO products

Article-12 (1) In order to use imported GMO and products in food or feed materials' production, food or feed processor, in the application for permission and registration must meet the criteria below, in addition to the food and feed legislation:

a) The following documents and information about the raw materials that are GMO or products must be submitted to the Ministry within one month.

1) Information about from whom and how much (material) is obtained,

2) In which way these products will be used.

3) Label or transcript of the required documents that must accompany GMO and products.

b) GMO food or feed must be processed in a line and stored in a place that is different from non-GMO food or feed line and storage area. If the same production line is used, it must be cleaned accordingly.

c) If there are perceived risks after the production, necessary precaution plans, and other extra precautions concerning transport and storage must be declared to the Ministry.

d) The requirements for safe disposal and destruction of waste and residues must be determined and declared to the Ministry.

Export of GMO Products

Article- 13 (1) In exports the request of the buyer country is noted and processes are carried out accordingly. If the importing country does not have any requests about GMO's, then general export legislation is used.

Labeling of Food

Article- 14 (1) According to the provisions of the legislation, if the allowed GMO food contains more than 0.9 % GMO; the following criteria must be used in labeling in addition to the Turkish Food Codex Legislation (published on the Official Gazette No:23172 on 11/16/1997):

a) If the GMO is composed of one component the labeling should contain "genetically modified" or the product name of the raw material name should contain "produced from...genetically modified...".

b) If the GMO is composed of multiple components in addition to "genetically modified..." or "produced from...genetically modified..." statements, the component list must have the above statements in parenthesis. Font size should be the same.

c) Bulk products must contain documents with labeling information.

d) In addition to the above mentioned labeling requirements, if the GMO food differs from the non-GMO food in regards to composition, nutritional effects, and nutritional values; the label must note these. It is required to have nutritional labeling for GMO foods with nutritional composition differences.

e) If the GMO food differs from the non-GMO food, the label should contain health warnings about health

risks that might arise from the use of these products.

Labeling of Feed

Article-15 (1) According to the provisions of the legislation if the allowed GMO feed or raw material of feed contain more than 0.9 % GMO, in addition to the feed labeling regulations, the following criteria must be used in labeling.

- a) GMO feed must have the statement “genetically modified...” next to its name. This statement could also be added as a foot note under the components. In this case, the font size should not be smaller than the font size of components.
- b) Feed made from GMO product must have the statements “produced from...genetically modified...” next to its name. This statement could be added as a foot note under the components. In this case the size of font characters should not be smaller than the font size components.
- c) Bulk feed must have documents with the labeling information.
- d) If the GMO feed differs from the non-GMO feed, the label must make note of composition, nutritional effects, usage purpose, and health declaration for specific animal kinds or categories.
- e) If there are no non-GMO equivalents for the feed that is produced by GMO's, the nature and the characteristics of the feed must be listed on the label.

Surveillance and traceability

Article-16 – (1) Importers or exporters, processors, storing facilities, distributors and retailers of GMO and products must keep records, ensure traceability, and keep unique identifier numbers and all necessary documents with the product, during/until the end of the process where the consumer obtains the products.

(2) Importers or exporters, processors, storing facilities, distributors and retailers of GMO and products must store necessary documents and information for 20 years and must have a record/archive system for these documents.

(3) Whether the conditions in the GMO and products decision document is followed, is inspected by officers assigned by the Ministry. If there are complaints, agencies assigned by the Ministry processes these in accordance with the articles of this legislation and regulations.

Inspection and control

Article-17 – (1) Inspection and control of GMO and products should be carried out according to the articles of this Legislation and according regulations.

SECTION-5

Others and Final Provisions

Sampling and analysis

Article-18 (1) Procedures about sampling and laboratory analysis of GMO food and feed is determined by the Ministry.

Punitive Articles

Article- 19 – (1) About not following the articles of the legislation:

- a) Law number 4703, articles 11 and 12,
 - b) Law number 5179, article 29,
 - c) Law number 1734, articles 12, 13, and14,
- action will be taken according to the above.

Implementation

Article-20 – (1) This legislation goes into effect immediately upon publishing date.

Execution

Article-21 - (1) The provisions of this Regulation is executed by the Minister of Agriculture and Rural Affairs.

**Press Statement by the Ministry of
Agriculture and Rural Affairs
on the Regulation on GMOs
October 27, 2009**

Turkey has three out of eight gene centers around the world. We currently have about 12,000 plant varieties and 3,905 of them are endemic. Turkey is the motherland of many significant crops including wheat, barley, chickpeas, lentils and olive.

GMO seeds, GMO food and GMO feed threatens our biodiversity and our sustainability. The GMO products are grown in 28 countries and the United States, Argentina, Brazil, China, Canada, India, Australia, New Zealand and South Africa are the leading producers of it. Therefore, in order to avoid our biodiversity to be damaged, the production of GMO seeds and related products is banned with "Regulation on the Import, Processing, Export, Control and Inspection of Food and Feed Products Bearing GMOs and GMO Components", which was published on the Official Gazette on October 26, 2009.

With this Regulation, the import of GMOs, GMO food and GMO feed are banned if they risk human and animal health and welfare and are against the consumer and environmental benefits and have antibiotics in themselves. The use of these products in baby formula is also banned.

The risk assessment will be conducted by an independent, scientific and technical committee of 11 members from TUBITAK, universities and researchers. The product must be labeled if it is proven scientifically by the committee for not holding risks to human health, animal health and welfare, consumer benefits and environment.

There are many penalties if the requirements of the Regulation are not met. The penalties include re-calling of the product, cancellation of the approval, monetary punishment and imprisonment. This is in accordance with the laws number: 4703, 5179 and 1734.

According to the Regulation, the Ministry will increase the frequency of market inspection and control during the export, import, processing, and transportation of the products in line with the committee's (independent, scientific, technical) report. Analysis will be done by our Ministry's laboratories and they will also be taken into consideration. If the results are against the Regulation, we will penalize the responsible parties.

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